EMORD & ASSOCIATES, P.C.
1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036
TELEPHONE: (202) 466-6937
TELECOPIER: (202) 466-6938

May 28, 1999

VIA TELECOPIER 202-260-8957
Naomi Kulakow
Center for Food Safety and Applied Nutrition (HFS-165)
Food and Drug Administration
200 C Street S.W.
Washington, D.C. 20204

Re: Meeting Registration
Docket No. 99N-1174
Dietary Supplements; CFSAN Strategy; Public Meeting

Dear Ms. Kulakow:

This letter amends the letter we forwarded to your office by telecopier on May 27, 1999. In that correspondence we provided the agency with the names of the business affiliations that Claudia A. Lewis-Eng of Emord & Associates would be representing at the FDA public meeting being held on June 8, 1999. We have an additional company to add to that list: Xcel HealthCare, Inc. Please add its name to FDA's list of companies being represented by Claudia A. Lewis-Eng at the June 8, 1999 public meeting.

If you have any questions or require additional information, please do not hesitate to contact us.

Sincerely,

Jonathan W. Emord

99N-1174

AMD1

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Re: Meeting Registration
Docket No. 99N-1174
Dietary Supplements; CFSAN Strategy; Public Meeting

Dear Ms. Kulakow:

This letter responds to the request for public participation at the June 8, 1999 meeting on dietary supplement regulation specified in the Notice of May 13, 1999, published in the above-referenced docket, 64 Fed Reg 25889. The following two attorneys wish to make oral presentations at the meeting on behalf of clients of Emord & Associates, P.C.

NAME: CLAUDIA A. LEWIS-ENG

Title: Attorney with Emord & Associates, P.C.

Business Affiliation: Attorney representing Mycology Research Labs Ltd.; Pure Encapsulations, Inc.; Weider Nutrition International, Inc.; Dr. Julian M. Whitaker; and Durk Pearson and Sandy Shaw

Address: Emord & Associates, P.C., 1050 17th Street, N.W., Suite 600, Washington, D.C. 20036 and Burke Professional Center, 5282 Lyngate Court, Burke, VA 22015

Telephone: 202-466-6937

Facsimile Number: 202-466-6938

Brief Statement of the General Nature of Arguments to Be Presented by Ms. Lewis-Eng: Ms. Lewis-Eng will address CFSAN's 1999 Program Priorities concerning development of an overall strategy for achieving effective regulation of dietary

supplements under the Dietary Supplement Health and Education Act. Ms. Lewis-Eng will recommend that the FDA implement fully and faithfully the decision of the United States Court of Appeals for the D.C. Circuit in *Pearson v. Shalala*. In particular, she will urge the agency to make it a top priority to approve with disclaimers, if necessary, all four claims presented by the petitioners in that case and to employ disclaimers as an alternative to outright suppression of claims that contain potentially, but not inherently, misleading representations.

Ms. Lewis-Eng will recommend that the agency reprioritize its enforcement efforts through FDA district offices nationwide to ensure that agency resources are expended to eliminate specific supplement products that have actually caused harm to the public because of adulteration or misbranding rather than devote those resources to pursue the more academic labeling disputes that are not directly linked to an imminent or actual public health threat. Ms. Lewis-Eng will explain that, given its limited resources, FDA has not enforced, and cannot expect to enforce, the law against every violator but instead must determine how best to pursue its overall agenda of protecting the public health through selective enforcement. In that regard, she will argue that vigorous pursuit of evidence against parties whose products have actually caused harm is preferable to neglecting those violators in favor of ones who may be guilty of offenses not directly tied to demonstrable harm to public health.

Ms. Lewis-Eng will also recommend that FDA's adverse event reporting system be revised to confirm the accuracy and reliability of reports before they are included in any public posting. Ms. Lewis-Eng will explain that there are no adequate checks at present to guard against misuse of the reporting system for wrongful purposes. She will point out that much data posted on the web is either false or misleading and defames and maligns innocent parties.

Length: 10 Minutes

NAME: STEVEN W. ALLIS

Title: Attorney with Emord & Associates, P.C.

Business Affiliation: Attorney representing Bio-Genics, Inc. d/b/a E'Ola International

Address: Emord & Associates, P.C., 1050 17th Street, N.W., Suite 600, Washington, D.C. 20036 and Burke Professional Center, 5282 Lyngate Court, Burke, VA 22015

Telephone: 202-466-6937

Facsimile Number: 202-466-6938

Address: Emord & Associates, P.C., 1050 17th Street, N.W., Suite 600, Washington, D.C. 20036 and Burke Professional Center, 5282 Lyngate Court, Burke, VA 22015

Telephone: 202-466-6937

Facsimile Number: 202-466-6938

Brief Statement of the General Nature of Arguments to Be Presented by Mr. Allis: Mr. Allis will address CFSAN's decision to make an "A" list priority completion of its rulemaking addressing dietary supplements that contain ephedrine alkaloids. Mr. Allis will explain that the agency's proposed rule is based to a significant extent upon unscientific information, the agency's adverse event reports. Because those reports are not corroborated, they cannot form a competent and reliable basis for taking proposed actions that would restrict the marketing and sale of a dietary supplement. Moreover, he will explain that in instances where ephedrine is misbranded or promoted for use as a street drug, the agency already possesses necessary and sufficient statutory and regulatory power to prosecute those law violators. Instead of imposing a broad prior restraint on labeling and use, based on an inadequate scientific record, FDA should instead make it a priority to enforce against specific parties that have misbranded or promoted drug use of ephedrine alkaloid products. Moreover, Mr. Allis will emphasize that the agency should avoid any action that would restrict use of synthetic ephedrine and favor herbal ephedrine in light of the fact that control of dosage amounts of ephedrine alkaloids in dietary supplement products depends on standardization of ephedrine herb extracts and is aided by use of synthetic ephedrine.

Length: 10 Minutes

Sincerely,

Jonathan W. Emord